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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,506	07/03/2003	Qingnong Tang	1370-2 DIV	6637
23869	7590	03/25/2004	EXAMINER	
HOFFMANN & BARON, LLP 6900 JERICHO TURNPIKE SYOSSET, NY 11791			TATE, CHRISTOPHER ROBIN	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 03/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/614,506	<b>Applicant(s)</b> TANG ET AL.	
	<b>Examiner</b> Christopher R. Tate	<b>Art Unit</b> 1654	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 July 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 31-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Claims 31-41 are presented for examination on the merits.

#### *Claim Rejections - 35 USC § 102/103*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 31-35 and 38 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Van Boven et al. (J. Agric. Chem., 1993).

A simmondsins extract (or food formulation comprising a simmondsins extract) is claimed.

Van Boven et al. teach the preparation of a simmondsin extract from deoiled jojoba meal (plant material) with acetone (a polar solvent) as well as with methanol (a polar solvent), whereby a simmondsin-rich extract portion is filtered over activated carbon, resulting in a light yellow solution (e.g., reasonably reads upon the liquid extract of claims 33 and 38, as well as claim 31). Van Boven et al. also teach subsequent crystallization of such a simmondsin -rich

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extract portion (e.g., reasonably reads upon the dry purified liquid extract of claims 32, 34, and 35, as well as claim 31) - see, e.g., page 1605, *Extraction of Simmondsin*.

Based upon the similar steps by which the reference simmondsin-rich extract is prepared vs. the instantly claimed/disclosed steps of preparing such an extract, including the step of exposing the crude simmondsin-containing extract to a carbonaceous adsorbant - i.e. activated carbon (which, as readily admitted by Applicants, would inherently remove simmondsin ferulate therefrom), the referenced simmondsin extract(s) appears to be identical to the presently claimed simmondsin extract(s). Consequently, the claimed simmondsin extract(s) appears to be anticipated by the reference (please note that nothing would preclude ingestion of such an extract and, thus, the extract preparations taught by Van Boven et al. reasonably reads upon the above cited food/animal feed claims).

In the alternative, even if the claimed simmondsin extract(s) is/are not identical to the referenced simmondsin extract(s) with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced simmondsin extract(s) is/are likely to inherently possess the same characteristics of the claimed simmondsin extract(s) (including inherently containing the levels of simmondsin and simmondsin ferulate instantly claimed) particularly in view of the similar process steps by which they were each prepared, as discussed above. Thus, the claimed simmondsin extract would have been obvious to those of ordinary skill in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

With respect to the USC 102/103 rejection above, please note that the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicants' simmondsin extract preparation(s) differs and, if so, to what extent, from those of the discussed reference. Therefore, with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants. In addition, please note that "the patentability of a product does not depend upon its method of production. If the product in [a] product-by-process claim is the same as or obvious from a product of the prior art, [then] the claim is unpatentable even though the prior [art] product was made by a different process." In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 218 USPQ 289, 292 (Fed. Cir. 1983).

***Claim Rejections - 35 USC § 103***

Claim 31-35 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abbott et al. (US 6,007,823).

Abbott et al. beneficially teach the selective extraction of one or more simmondsin components (such as simmondsin) from deoiled jojoba meal including via the use of several types of polar extraction solvents (e.g., water and/or ethanol) so as to prepare simmondsins extract preparations containing various levels of simmondsin and simmondsin ferulate therein. Abbott et al. further teach separation/purification of particular simmondsin fractions from such extract preparations including separating/purifying a simmondsin-rich extract fraction "containing greater than 90% pure simmondsin" therein, which Abbott et al. teach can be used in a liquid or dried state (see entire document including Figures, col 2, line 38 - col 6, line 2). Please note that based upon the separation/purification schemes taught by Abbott et al., such a selective simmondsin-rich product would intrinsically contain less than 3% simmondsin ferulate therein. Abbott et al. also beneficially disclose that it is well known in the art to use simmondsin as an effective hunger satiation agent in reducing food intake, and that although jojoba meal has been used for its simmondsin content to regulate food intake of animals, the meal contains various undesirable ingredients therein including bitter taste factors, among others (see, e.g., col 1, lines 20-26).

Although Abbott et al. do not expressly teach preparing a debittered simmondsin extract containing the levels of simmondsin and simmondsin ferulate instantly claimed, based upon the overall beneficial teachings provided therein (as discussed above) the adjustment of such levels (such as preparing a simmondsin-rich extract preparation containing 90-91% simmondsin, as well as further removing undesirable simmondsin ferulate therefrom - e.g., for use as a hunger satiation agent within a food/animal feed), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Thus, the invention as a whole is *prima facie* obvious over the reference, especially in the absence of evidence to the contrary. [Again, with respect to claims 32-35 and 38, please note that in product-by-process claims, the “patentability of a product does not depend on its method of production.” *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985); *In re Marosi*, 218 USPQ 289, 292 (Fed. Cir. 1983)].

Claims 31-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abbott et al. (US 6,007,823), in view of Van Boven et al. (J. Agric. Food Chem., 1993) and Van Boven et al. (J. Chromatogr. B: Biomed. Appl., 1994), and further in view of Jones et al. (US 5,962,043).

Abbott et al. is relied upon for the reasons discussed *supra*. Abbott et al. do not teach mixing such polar extract solvent preparations with an adsorbent such as activated carbon.

The 1993 reference by Van Boven et al. are relied upon for the reasons discussed *supra*.

The 1994 reference by Van Boven et al. teaches treating a liquid Simmondsins extract (plasma) by mixing it in a suspension of water (solvent) and activated carbon, vortexing the mixture, separating the activated carbon therefrom, including optionally eluting therefrom with a solvent such as a short chain alcohol, ethyl acetate, etc., and subsequently drying the liquid residue by evaporation (see, e.g., paragraph bridging pp. 282-283). In addition, Van Boven et al. (1994) teach that their procedure for obtaining simmondsin as discussed above [e.g., via mixing a simmondsin-containing sample in a suspension of water (solvent) and activated carbon, vortexing the mixture, separating the activated carbon therefrom] allows for a very effective, sensitive, and selective method of extracting simmondsin from aqueous/liquid solutions, where

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other solvent-solvent extraction methods did not result in any significant recovery of simmondsin (see entire document including pages 282-283, and conclusion on page 284).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the process of obtaining a simmondsin-rich extract preparation disclosed by Abbott et al. by incorporating one or more of the steps taught by the Van Boven et al references - including mixing one or more of the simmondsin-containing extraction solvents of Abbott et al. with activated carbon, vortexing the mixture, and separating the activated carbon therefrom - as discussed above, for the beneficial teachings therein with respect to providing an effective, sensitive, and efficient means of obtaining a liquid or dried extract residue which contains high amounts of simmondsin therein, which is the desired goal of the Abbott et al. process (especially with respect to simmondsin-rich extract preparations for use in food/animal feed). The result-effective adjustment of particular conventional working conditions (preparing such simmondsin-rich extract preparations containing appropriate/desirable amounts and/or ratios of simmondsin and simmondsin ferulate therein - e.g., within a food/animal feed formulation; as well determining a suitable amount of such a simmondsin extract preparation to add to a food/animal feed, based upon the express teachings provided by Jones et al. with respect to appropriate percentage amounts/ratios of simmondsin component therein - see entire document including abstract), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan having the cited references before them.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

### Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached at (571) 272-0961.



Christopher R. Tate  
Primary Examiner, Group 1654